PDB38

THE EFFECT OF WEIGHT CHANGES ON HEALTH-RELATED QUALITY OF LIFE AND WORK IMPAIRMENT IN PATIENTS WITH TYPE 2 DIABETES

Krishnarajah G[1], DiBonaventura M[2], Wagner S[3], Gupta S[4]

[1]Bristol-Myers Squibb, Princeton, NJ, USA, [2]Consumer Health Sciences, new York, NY, USA, [3]Consumer Health Sciences International, Princeton, NJ, USA, [4]Consumer Health Sciences, Princeton, NJ, USA

OBJECTIVES: To investigate whether patients with type-2 Diabetes Melittus (T2DM) who gained ≥5% of their bodyweight over the course of one year experienced changes in health-related quality of life (HRQoL) and work impairment relative to those who lost ≥5% of their bodyweight. **METHODS:** Data were taken from the 2006 and 2007 National Health & Wellness Survey, an annual, cross-sectional, Internet survey of US adults. All patients in survey with T2DM whose 2006–2007 weight gain was ≥5% of their bodyweight (n = 300) were compared to those whose weight loss was ≥5% of their bodyweight (n = 330) on levels of HRQoL (assessed with the SF-8 and SF-12 for 2006 and 2007, respectively) and levels of work impairment (assessed with the Work Productivity and Activity Impairment Questionnaire (WPAI)) in a series of multiple regressions, controlling for demographics, volitional weight loss (whether or not respondents were taking steps to lose weight), and comorbidities. **RESULTS:** It was shown that weight gain was associated with significantly lower levels of the SF-12 Physical Component Summary (mean score (M) = 39.6 vs. M = 41.5, $p < 0.01$). Among obese respondents, this effect was amplified (M = 37.6 vs. M = 40.3, $p < 0.01$). No significant differences were found between T2DM patients who gained ≥5% of their weight and those who lost ≥5% of their weight on Mental Component Summary (M = 48.6 vs. M = 47.9, $p = 0.34$), absenteeism (mean impairment (M) = 4.6% vs. M = 1.8%, $p = 0.32$), presenteeism (M = 18.9% vs. M = 14.3%, $p = 0.26$), total work impairment (M = 20.1% vs. M = 16.6%, $p = 0.46$), or activity impairment (M = 33.8% vs. M = 31.4%, $p = 0.22$), though most effects were in the expected direction. **CONCLUSIONS:** T2DM patients who gained weight, especially for obese individuals, reported significantly lower levels of HRQoL relative to those who lost weight. Treatments that avoid weight gain and/or promote weight loss could have a beneficial impact beyond HgbA1c for T2DM patients.

PDB39

DEVELOPMENT OF A VALUATION FUNCTION FOR A DIABETES-SPECIFIC PREFERENCE-BASED MEASURE OF HEALTH BASED ON THE MULTI-ATTRIBUTE UTILITY THEORY

Sundaram M[1], Smith MJ[2], Revicki D[3], Miller LA[4], Madhavan SS[2]

[1]QualityMetric Incorporated, Lincoln, RI, USA, [2]West Virginia University, Morgantown, WV, USA, [3]United BioSource Corporation, Bethesda, MD, USA, [4]University of Texas M.D. Anderson Cancer Center, Houston, TX, USA

OBJECTIVES: The Diabetes Utility Index (DUI) is a brief, self-administered diabetes-specific PBMH. We describe the development of the valuation function for the DUI and report its validity. **METHODS:** MAUT identified 20 of 768 DUI health states (anchor states, single-attribute level states, and marker states) for which preferences were then elicited via Visual Analog Scale and Standard Gamble (SG) tasks during personal interviews of individuals with diabetes recruited from primary care and community settings around Morgantown, WV. A valuation function calculating utilities for all DUI health states and attribute-level utilities was developed. A DUI validation survey was mailed in collaboration with the West Virginia University Diabetes Institute. Clinical data (ICD-9 codes and A1C values) and other self-reported data were merged with function-derived DUI utilities. **RESULTS:** Employing MAUT, a DUI valuation function between 1.00 = Perfect Health and 0.00 = the all worse "Pits" state (adjusted to yield utilities between 1.00 = Perfect Health and 0.00 = Dead) was developed from data on 100 interviewees. A total of 396 persons with diabetes completed the validation survey (33% response). The DUI valuation function-derived utilities compared favorably to cardinal SG utilities obtained directly on three DUI health states, but slightly underestimated SG utilities for mild and moderate health states (mean absolute difference = 0.05). There was a small correlation between DUI utilities and average A1C values ($r = -0.30$, $p < 0.001$). Respondents with two or more complications had lower DUI utilities than those with none ($p < 0.001$) or one complication ($p = 0.015$). Insulin users had lower DUI utilities compared to non-users ($p < 0.001$), and those with A1C under 7 had higher DUI utilities than those with A1C of 7 or greater ($p < 0.001$). **CONCLUSIONS:** These results provide initial evidence of the DUIs feasibility and validity. Further research will demonstrate the generalizability of these findings, show the responsiveness of the DUI, and report the clinical meaningfulness of DUI change scores.

PDB40

THE IMPACT OF FREQUENCY AND SEVERITY OF SELF-REPORTED HYPOGLYCEMIA ON QUALITY OF LIFE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS TREATED WITH ORAL ANTI-HYPERGLYCEMIC AGENTS

Marrett E, Zhang Q, Radican L

Merck & Co., Inc., Whitehouse Station, NJ, USA

OBJECTIVES: Hypoglycemia is a side-effect of treatment with oral anti-hyperglycemic agents (OAHAs), especially sulfonylureas (SU). This study assessed the impact of self-reported hypoglycemia on health-related quality of life (HRQoL) among patients with type-2 diabetes mellitus (T2DM), treated with OAHAs. **METHODS:** A cross-sectional, internet-based study was conducted among 2008 participants from the US National Health and Wellness Survey 2007. Patients with self-reported T2DM treated with OAHAs only were included. For each level of self-reported hypoglycemic severity (mild, moderate, severe), frequency (1 to 2 episodes, 3 to 6 episodes, or > than once per month) data for six months prior to survey were collected. Very severe hypoglycemia (medical assistance required) was recorded as either one episode or >= to two episodes. Utility was measured using the EQ-5D, and fear of hypoglycemia using the Worry subscale of the Hypoglycemia Fear Survey II (HFS). **RESULTS:** Mean age was 58 (±11) years, 43% were female, and 72.2% reported HbA1c goal attainment (<7%). The proportions of patients on SU monotherapy, SU combination therapy, and other treatment regimens were 10.7%, 39.7%, and 49.6%, respectively. Hypoglycemic episodes were reported by 61.6% of patients (45.6% mild, 37.4% moderate, 13.2% severe and 3.8% very severe). After adjusting for age, gender, weight gain, microvascular and macrovascular complications, the utility scores decreased by increasing severity and frequency of hypoglycemic episodes (with reference = no hypoglycemia), i.e., 0.008, 0.013, 0.015 for mild respectively, 0.046, 0.061, 0.11 for moderate, 0.089, 0.16, 0.27 for severe, and 0.17, 0.27 for very severe, whereas HFS scores increased, 4.6, 5.5, 7.8 for mild, 11.4, 15.2, 13.8 for moderate, 15.5, 20.1, 25.5 for severe, and 25.6, 26.6 for very severe. **CONCLUSIONS:** Self-reported hypoglycemia was experienced by over half of the patients on OAHAs and was associated with reduced quality of life. The magnitude of the reduction increased with frequency and severity of hypoglycemic episodes.

PDB41

THE HANDLING OF GLUCOSE MONITORING AND INSULIN TREATMENT (HAGLUMIT) QUESTIONNAIRE CAPTURES HANDLING DIFFERENCES BETWEEN DIFFERENT SITUATIONS AND SYSTEMS FOR MONITORING BLOOD GLUCOSE IN DIABETES

Mast O[1], Schmidt U[2]

[1]Roche Diagnostics, Ltd, Mannheim, Germany, [2]Roche Diagnostics, Ltd, Mannheim, Baden-Württember, Germany

OBJECTIVES: Evaluate difficulties in handling Self Monitoring of Blood Glucose (SMBG) from a patient's perspective under normal and stressed conditions, using a new strip-free SMBG system. **METHODS:** The newly developed HaGluMIT questionnaire captures patient-reported ease of performing 9 typical steps in the SMBG process (7-point scale: 1 (very easy) to 7 (very difficult)). Fifty insulin treated diabetes patients participating in a 2-week product evaluation study used the new Accu-Chek Mobile system in parallel to their current SMBG systems. They were asked to voluntarily fill out HaGluMIT at the beginning (current system) and the end (new system). **RESULTS:** Thirty-six subjects completed both questionnaires and were eligible for comparative analysis (1 missing pre-evaluation and 13 missing post-evaluations). Mean SMBG duration was 14 years with currently 5.7 tests per day. Twenty-three subjects were using an insulin pump. Data logging (2.68) was perceived to be most difficult to handle under normal conditions followed by teststrip vials (2.44), lancets (2.26), carrycase (2.10), teststrips (2.06), meter (1.97), blood application (1.94), lancet device (1.91) and insulin application (1.75). Under stressed conditions scores increased an average of 0.68 points. Post-evaluations demonstrated statistically significant improvements for lancets, blood application and data logging under normal and stressed conditions in favor of the new system. The impact of stress was lower (average increase: 0.59 points). **CONCLUSIONS:** A number of patient reported handling problems in performing SMBG are reported in former research. This might result in skipping tests or making decisions based on inaccurate measures. Data logging is perceived to be most difficult to handle, followed by lancets, teststrips/vials and carrycase. HaGluMIT captures changes in handling difficulty. Stress (e.g. from public attention, time pressure or hypoglycemic states) increases the difficulty of handling. An integrated SMBG system without single strips and lancets significantly improved handling difficulties under normal and stressed conditions.

PDB42

PERCEPTION VERSUS REALITY – CATEGORISATION OF PATIENT WEIGHT BY TYPE 2 DIABETES (T2DM) PATIENTS AND THEIR PHYSICIANS IN THE US AND EUROPE

Stahl E[1], Benford M[2], Leith A[2], Colclough HA[3], Watmough A[2], Grandy S[4]

[1]AstraZeneca R&D Lund, Lund, Sweden, [2]Adelphi Group Products, Bollington, Cheshire, UK, [3]Adelphi Group Products, Chesire, UK, [4]AstraZeneca, Wilmington, DE, USA

OBJECTIVES: The objective was to understand how type-2 diabetes mellitus (T2DM) patients and their physicians perceive weight in relation to the objective measure of body mass index (BMI). **METHODS:** Analysis was performed using data from the Adelphi Diabetes Disease Specific Programme (DSP©), a large cross-sectional study of clinical and treatment practice. Physicians (diabetologists and primary care practitioners) provided clinical assessment and information on T2DM patients. All physicians and consenting patients were required, separately, to categorise patient weight as: normal, overweight, severely overweight/obese, severely obese. Physicians also provided height and weight for patients but were not required to calculate BMI. Physician and patient estimates were subsequently compared with calculated BMI for each patient. **RESULTS:** A total of 132 (US) and 511 (5 EU countries) physicians participated. Physicians categorised the weight of 928 (US) and 3969 (EU) T2DM patients for whom BMI was calculated. Equivalent matched numbers of patients categorising their weight was 626 (US) and 2013 (EU). Patient mean age was 62 years; duration of T2DM 6 years; 51% were male; 55% in US and 33% in EU were obese (BMI >/= 30). Across all weights, some patients' weight category was underestimated by their physicians (US 38% underestimated vs. 54% correct; EU 21% vs. 69%). T2DM patients were more likely to underestimate their weight (US 60% underestimated vs. 37% correct, EU 43% vs. 51%). Discrepancies in weight estimation were greatest for countries where overall mean BMI was >30 (US, UK) and least

where mean BMI was lowest (Italy). **CONCLUSIONS:** Weight control is an important aspect of management of T2DM. This requires accurate assessment and agreement of patient weight and BMI levels by treating physicians and their patients. Accurate risk stratification based on weight and BMI may help improve effective communications and disease management decisions between T2DM patients and their treating physicians.

PDB43

PATIENT REPORTED OUTCOMES ARE SUPERIOR IN PATIENTS WITH TYPE 2 DIABETES TREATED WITH LIRAGLUTIDE AS COMPARED TO EXENATIDE, WHEN ADDED TO METFORMIN, SULFONYLUREA OR BOTH

Schmidt WE[1], Christiansen JS[2], Hammer M[3], Zychma MJ[4], Buse J[5]

[1]Ruhr University, Bochum, Germany, [2]Århus University Hospital, Århus, Denmark, [3]Novo Nordisk A/S, Bagsværd, Denmark, [4]Novo Nordisk A/S, Bagsvaerd, Denmark, [5]University of North Carolina School of Medicine, Chapel Hill, NC, USA

OBJECTIVES: New treatments for T2D are needed to improve glycemic control, reduce side-effects, and improve patient satisfaction. Liraglutide is an OD human GLP-1 analog that has benefits as monotherapy, or in combination with OADs. **METHODS:** The Liraglutide Effect and Action in Diabetes 6 (LEAD-6) trial was an open-label trial comparing liraglutide to exenatide as add-on to OADs. Adults with T2D on metformin and/or sulfonylurea and A1C 7–11% were randomized to liraglutide 1.8 mg OD or exenatide 10 µg BD for 26 weeks. This was followed by a 14-week extension phase, in which all patients received liraglutide 1.8mg OD. **RESULTS:** During weeks 0–26, A1C reductions were significantly greater and the incidence of hypoglycemia was significantly lower in the liraglutide-treated group. Patient Reported Outcomes were measured in 379 patients using Diabetes Treatment Satisfaction Questionnaire status (DTSQs) at week 0, 26, 34 and 40 and DTSQ change (DTSQc) at week 26 and 34. The overall treatment satisfaction was highest with liraglutide ($p < 0.0001$); DTSQs score increased from 27.4 at baseline to 32.1 at week 26 compared to exenatide (increase from 27.6 to 29.3). All items on DTSQs except 'understanding' (ie 'current treatment', 'convenience', 'flexibility', 'recommend', 'continue') improved significantly more with liraglutide than exenatide. The proportion of 'satisfied' patients (defined as DTSQc > 6) was 94% in liraglutide, 86% with exenatide ($p = 0.0176$). Patients perceived a greater reduction in hypoglycemia at week 26 with liraglutide (DTSQc –0.9) than with exenatide (–0.4; $p = 0.0193$) and a greater reduction in perceived hyperglycemia (–1.0, –0.3, respectively; $p = 0.0007$). During the extension phase, when all patients received liraglutide, DTSQs scores remained stable in patients who continued on liraglutide and had increased significantly ($p = 0.0131$) at week 40 in those who switched from exenatide to liraglutide at week 26. **CONCLUSIONS:** These results demonstrate significant improvements in patients' treatment satisfaction with liraglutide compared to exenatide.

PDB44

EFFECTS OF INSULIN THERAPY ON THE DIABETES SYMPTOM CHECKLIST-REVISED (DSC-R): DATA FROM A LARGE INSULIN CLINICAL TRIAL

Nelson L[1], McLeod LD[1], Lee LJ[2], Hill C[1], Sweeney C[1], Sun P[3], Fahrbach J[2], Martin S[2], Weinstock RS[4]

[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA, [3]Kailo Research Group, Indianapolis, IN, USA, [4]SUNY Upstate Medical University and the Department of Veterans Affairs Medical Center, Syracuse, NY, USA

OBJECTIVES: To examine the impact of insulin initiation on the DSC-R in patients with type 2 diabetes (T2D). **METHODS:** We administered the DSC-R to T2D patients enrolled in a large insulin clinical trial (acronym: DURABLE) at baseline prior to starting insulin and at six months post-insulin initiation. The trial compared the efficacy and safety of insulin initiation with lispro mix 75/25 versus insulin glargine. The DSC-R is a T2D-specific measure that assesses the occurrence and the perceived burden of the following eight T2D-related symptoms: hypoglycemic, hyperglycemic, cardiovascular, neuropathic/pain, neuropathic/sensory, psychological/fatigue, psychological/cognitive, and ophthalmologic/vision. Summary score for each domain ranged from 0–100 with higher scores indicating greater symptom burden. We compared change in mean score (baseline to six months) for two insulin arms combined together. Effect size (ES; cohen's d) and analysis of covariance were used to examine the extent and significance of change. Effect sizes of 0.2, 0.5, and 0.8 represent small, medium, and large degrees of change, respectively. **RESULTS:** A total of 576 patients completed the DSC-R at both time points. The mean age, duration of diabetes, A1c, and percent female at baseline were 57.0 years, 9.6 years, 8.9%, and 41%, respectively. Baseline mean scores ranged from 24.2 (cardiovascular and neuropathic/pain) to 45.9 (psychological/fatigue). The mean scores at 6 months ranged from 22.6 (ophthalmologic/vision) to 40.7 (psychological/fatigue). Absolute changes in the mean domain score ranged from +0.6 (neuropathic/sensory) [$p = 0.45$; ES = 0.02] to –9.8 (hyperglycemic) [$p < 0.0001$; ES = 0.38; small to medium effect]. Other domains with ES ≥0.20 were psychological/fatigue and psychological/cognitive. **CONCLUSIONS:** Initiation of insulin therapy was associated with a small to moderate improvement in hyperglycemic symptoms domain. Small effects were also observed in psychological/fatigue and psychological/cognitive domains.

PDB45

SATISFACTION WITH DIABETES TREATMENTS: IMPACTS ON PATIENT HEALTH-RELATED QUALITY OF LIFE AND PRODUCTIVITY

Pollack M[1], Waterman F[2], Bolge SC[3], Williams S[4]

[1]AstraZeneca, LP, Wilmington, DE, USA, [2]Consumer Health Sciences, New York, NY, USA, [3]Consumer Health Sciences International, Princeton, NJ, USA, [4]AstraZeneca, Wilmington, DE, USA

OBJECTIVES: Diabetes is a debilitating and common illness that can lead to significant disability. Key patient-reported outcomes are important as they can influence productivity and patient health-related quality of life (HRQL). The objectives of the current research were to: (1) assess the current level of treatment satisfaction within existing oral anti-diabetics (OADs) and (2) determine the association between treatment satisfaction and productivity and HRQL. **METHODS:** The current study design was a cross-sectional web-based survey of adults diagnosed with type 2 diabetes mellitus (T2DM) using OADs, but not insulin. Treatment satisfaction was assessed using the Diabetes Medication Satisfaction questionnaire (DiabMedSat). HRQL was examined with the EQ-5D instrument. The Work Productivity and Activity Impairment (WPAI) and Diabetes Productivity Measure (DPM) questionnaires were used to assess productivity. Pearson's correlations and linear regression models were used to assess strength and direction in association. **RESULTS:** Of 2,074 survey respondents, 53% were men and mean age was 60 years (SD = 10.83). 64% of respondents report being very/extremely satisfied with their diabetes treatments. Total DiabMedSat score was 79.5; higher scores were reported with the burden subscale (89.5) versus the efficacy and symptom (i.e. tolerability) sub-scales (69.8 and 69.5). There was a direct correlation between overall treatment satisfaction and higher EQ-5D scores ($r2 = -0.401$, $p < 0.001$), and increased work and life productivity (DPM: $r2 = 0.595$ and $r2 = 0.640$, $p < 0.001$). Similar correlation results were observed with WPAI. After controlling for patient demographics, treatment satisfaction has greater effects on presenteeism (impairment while working) (WPAI: –0.472, 95% CI: –0.611 to –0.333, $p < 0.001$) than absenteeism (missed work time) (WPAI: –0.057, 95% CI: –0.157 to 0.043, $p = 0.263$). **CONCLUSIONS:** Among T2DM patients, there is a high level of satisfaction with OAD therapies, though improvements could be made in efficacy and tolerability. Increases in treatment satisfaction can have a direct improvement on productivity and health-related quality of life.

PDB46

CONTRIBUTIONS OF AND RELATIONSHIP BETWEEN EXPECTATIONS ABOUT AND EXPERIENCES WITH INSULIN THERAPY TO TREATMENT SATISFACTION IN INSULIN-NAÏVE PATIENTS WITH TYPE-2 DIABETES

Naegeli AN, Hayes RP

Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To assess the relationship between patients' expectations about and experiences with insulin therapy, and how they contribute to overall treatment satisfaction. **METHODS:** The Expectations about Insulin Therapy (EAITQ) and the Experience with Insulin Therapy Questionnaires (EWITQ) were administered at baseline and endpoint, respectively, to insulin-naïve patients with type-2 diabetes in a randomized controlled trial comparing treatment algorithms for an inhaled insulin. Pearson correlation coefficients were calculated between EAITQ and EWITQ scores and patient characteristics and patient reported outcomes measures. Wilcoxon Signed Rank test was used to compare EAITQ and EWITQ item score distributions. Differences between EAITQ and EWITQ scores were calculated to categorize patients into three groups according to the extent to which their expectations about insulin therapy were met by experiences (i.e., not met, met, and exceeded). Oneway analysis of variance with Scheffe post-hoc tests was performed to detect differences in treatment satisfaction scores among the three groups. **RESULTS:** EAITQ and EWITQ data were available for 240 patients (male: 61% male, age: 58 (mean) years old, diabetes duration: 10 years, HbA1c: 8.4%). More positive expectations were significantly associated with greater self-efficacy ($p < 0.01$); more positive experiences were significantly associated with shorter diabetes duration, less symptom distress and greater well-being, self-efficacy, and treatment satisfaction ($p < 0.01$). Overall, patients' experiences with insulin therapy were significantly more positive than their expectations, with 58% of patients' experiences exceeding expectations, 29% experiences met by expectations, and 13% experiences less than expectations. Post-hoc tests indicated that diabetes treatment satisfaction scores were significantly different among the three groups with higher scores associated with the exceeding of expectations by experiences. **CONCLUSIONS:** Expectations may not independently impact treatment satisfaction, but their relationship with experiences significantly contributes to treatment satisfaction. The EAITQ and EWITQ may be useful tools for clinicians in identifying differences in expectations and experiences concerning insulin therapy.

PDB47

THE ASSOCIATION BETWEEN PATIENT-REPORTED DIABETES SYMPTOMS AND TOLERABILITY ISSUES OF ORAL ANTIDIABETIC AGENTS ON WORK AND LIFE PRODUCTIVITY

Pollack M[1], Bolge SC[2], Williams S[1], Waterman F[3]

[1]AstraZeneca, Wilmington, DE, USA, [2]Consumer Health Sciences International, Princeton, NJ, USA, [3]Consumer Health Sciences, New York, NY, USA

OBJECTIVES: Diabetes symptoms and tolerability issues of existing treatments may affect work productivity, contributing to the overall burden of type-2 diabetes mellitus (T2DM). Objectives were to document the frequency of diabetes symptoms and tolerability issues among existing oral antidiabetic drugs (OAD) and determine their